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| 10/734,954 | 12/12/2003 | Carlos Negroni | 60,210-210 | 1460 |

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| EXAMINER |
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APANIUS, MICHAEL

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| ART UNIT | PAPER NUMBER |
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3736

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS | 02/16/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

| | | | |
|------------------------------|-----------------|-----------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/734,954 | NEGRONI, CARLOS | |
| | Examiner | Art Unit | |
| | Michael Apanius | 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/12/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: "64" in figure 1 and "33" in figure 3. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The disclosure is objected to because of the following informalities:
- a. At paragraph 4, line 1, "an access cannulas" is improperly worded.
 - b. At paragraph 32, line 3, "style" should be --stylet--.

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- c. At paragraph 37, the recitations of "the interior surface 70" should be --the interior surface 78--.
- d. At paragraph 43, line 6, "the cutting edge 34" should be --the cutting edge 84--.
- e. At paragraph 45, line 2, "the sidewall 86" should be --the sidewall 76--.
- f. At paragraph 47, line 6, "limitation the" should be --limitation of the--.

Appropriate correction is required.

Claim Objections

- 3. Claims 17-24 are objected to because of the following informalities: at claim 16, line 2 and at claim 17, line 2, it appears that the semi-colon should be a colon.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 5. Claims 1-7, 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) in view of Tretinyak (US 4,403,617).
- 6. Mittermeier disclose a biopsy assembly (figure 1) for insertion into a mass of bone (100) to collect a biopsy specimen (104) of tissue therefrom, comprising: a

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cannula handle (44) having a passageway (46) extending therethrough from a support end to a receiving end defining a recess (on each side of 48 as shown in figure 1) disposed about said passageway; an access cannula (22) having a proximal end supported in said passageway and extending therefrom to an open end (32); an introduction stylet (26) for selective insertion into said passageway and through said access cannula for advancing said access cannula into the mass of bone to establish a biopsy harvest site (102); a cap (88) supporting said stylet; and an inner cannula (24) for selective insertion through said passageway into said access cannula and extending from a proximal end to a distal end (52).

7. In regards to claim 7, Mittermeier discloses a tool handle (56) connected to said proximal end of said inner cannula. In regards to claim 12, the cannula handle and said cap present a tongue and groove connection (49 and 58) for engaging upon rotation of said cap relative to said handle. In regards to claim 15, Mittermeier discloses an obturator (28) for selective insertion through said inner cannula to remove the biopsy specimen therefrom.

8. Mittermeier does not expressly disclose that the inner cannula has a swaged portion having a non-deformable sidewall with a frustoconical interior surface extending radially inwardly at a predetermined angle from said distal end to a biopsy opening.

9. Tretinyak teaches a cannula portion (see figures 2, 5-7) extending from a distal end for retaining a biopsy specimen therein and having a non-deformable sidewall (12) with a frustoconical interior surface (column 3, lines 8-12) extending radially inwardly at a predetermined angle from the distal end to a biopsy opening (see opening in figure 2)

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for receiving the biopsy specimen therethrough. The sidewall includes an exterior surface and said biopsy opening includes an annular cutting edge having a pair of beveled facets (column 3, lines 12-14) extending between said exterior surface and said edge for rendering said edge sharp. The facets converge at said cutting edge to define a pair of opposed cusps (at 12.4 and 12.5) extending therefrom.

10. Tretinyak does not expressly disclose that the distal portion is swaged. However, it is noted that regardless of how the distal portion was formed, the reference discloses a distal portion that is substantially equivalent to the claimed swaged portion and therefore is considered to meet the claim language.

11. The cannula portion of Tretinyak is capable of faster and smoother penetration so that a substantially undistorted tissue specimen is obtained (column 4, lines 35-51).

12. Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the inner cannula of Mittermeier to include the cannula portion of Tretinyak in order to more readily penetrate bone and to obtain a substantially undistorted tissue specimen.

13. Although Tretinyak discloses that the distal portion tapers inward, Tretinyak does not expressly disclose that the distal portion tapers at an angle of two degrees as set forth in claims 4 and 6. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to taper the distal portion at an angle of two degrees because Applicant has not disclosed that this particular angle (as opposed to another small angle) provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art,

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furthermore, would have expected Applicant's invention to perform equally well with a small but undisclosed angle as taught by Tretinyak because it improves cutting and will also help maintain the biopsy sample in the cannula. Therefore, it would have been an obvious matter of design choice to modify Tretinyak to obtain the invention as specified in claims 4 and 6.

14. Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) as modified by Tretinyak (US 4,403,617), as applied to claims 1-7, 12 and 15 above, and further in view of Strasser et al. (US 4,838,282). Mittermeier as modified by Tretinyak does not expressly disclose a luer connector on the tool handle for connection to a syringe. Strasser teaches connecting a syringe to a luer connector of a tool handle in a conventional manner for applying a vacuum to a cannula for drawing in and retaining a biopsy specimen within the cannula (column 8, lines 26-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the assembly of Mittermeier as modified by Tretinyak to include a luer connection on the tool handle for connection to a syringe in order to apply a vacuum to draw a sample into the cannula and retain the sample therein.

15. Claims 10, 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) as modified by Tretinyak (US

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4,403,617), as applied to claims 1-7, 12 and 15 above, and further in view of Jamshidi (US 5,807,275).

16. In regards to claims 10 and 11, Mittermeier discloses opposed fingers (48) on the cap for selectively engaging a ridge or tube (60). Mittermeier does not expressly disclose that the opposed fingers engage male luer threads. Jamshidi teaches male luer threads (22) about a receiving end of a cannula for the purpose of providing means to connect the cannula with an aspirator apparatus (column 5, lines 44-46). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have used male luer threads as taught by Jamshidi in place of the ridge or tube of Mittermeier as modified by Tretinyak in order to provide a more versatile connection that can be connected to other components such as an aspirator apparatus.

17. In regards to claims 13 and 14, Mittermeier as modified by Tretinyak does not expressly disclose a plurality of grooves and a plurality of tongues. Jamshidi teaches a tongue and groove connection having a plurality of grooves (40) extending radially into a cannula handle and a plurality of tongues (42) extending radially from a cap for engaging the grooves upon rotation of the cap relative to the handle. The tongue and groove configuration of Jamshidi provides a stop to ensure alignment and proper connection of the handles (column 4, lines 58-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the tongue and groove connection of Mittermeier as modified by Tretinyak to include a plurality of tongues and a plurality of grooves as taught by Jamshidi in order to provide a stop to ensure alignment and proper connection of the handles.

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18. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) as modified by Tretinyak (US 4,403,617) and Jamshidi (US 5,807,275), as applied to claims 10, 11, 13 and 14 above, and further in view of Strasser et al. (US 4,838,282). Mittermeier as modified by Tretinyak and Jamshidi discloses the limitations of claim 16 as noted above. However, Mittermeier as modified by Tretinyak and Jamshidi does not expressly disclose a luer connector on the tool handle for connection to a syringe. Strasser teaches connecting a syringe to a luer connector of a tool handle in a conventional manner for applying a vacuum to a cannula for drawing in and retaining a biopsy specimen within the cannula (column 8, lines 26-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the assembly of Mittermeier as modified by Tretinyak and Jamshidi to include a luer connection on the tool handle for connection to a syringe in order to apply a vacuum to draw a sample into the cannula and retain the sample therein.

19. Claims 17-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) as modified by Tretinyak (US 4,403,617), as applied to claims 1-7, 12 and 15 above, and further in view of Akerfeldt (US 5,868,684). Mittermeier as modified by Tretinyak discloses a method (Mittermeier: column 7, line 10 - column 8, line 9) of collection a biopsy specimen of tissue from a bone, comprising the steps of: inserting (fig 2) an introduction stylet through an access cannula to close an open end of the access cannula, inserting (fig 12) the stylet and access cannula into a

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bone to establish a harvest site therein, removing the introduction stylet from the access cannula whereby the access cannula maintains an access pathway to the harvest site; providing an inner cannula extending from a proximal end to a distal end; providing a portion of the inner cannula having a non-deformable sidewall having an exterior surface and a frustoconical interior surface (see Tretinyak) extending radially inwardly at a predetermined angle from the distal end to converge at a continuous annular cutting edge defining a biopsy opening; inserting (figures 13 and 14) the inner cannula into the access cannula, advancing (figures 13 and 14) the access and inner cannulas, a predetermined distance into the bone whereby the cutting edge severs a specimen from the bone and urges the specimen through the biopsy opening into the inner cannula, removing the inner cannula from the bone, and removing the specimen from the inner cannula.

20. Mittermeier as modified by Tretinyak does not expressly disclose extending the cutting edge through the open end. However, it would have been obvious to one having ordinary skill in the art at the time of invention that the cannula portion of Tretinyak would be extended past the open end of the access cannula of Mittermeier to cut and obtain a biopsy sample.

21. Mittermeier as modified by Tretinyak does not expressly swaging the portion of the inner cannula. Akerfeldt teaches that it is known in the art to use a swaging process to obtain a reduced diameter tapering portion (column 3, lines 21-55). Furthermore, it is noted that the process by which the distal cannula portion is formed is not critical to the claimed invention or to the invention of the cited references. Therefore, it would have

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been obvious to one having ordinary skill in the art at the time of invention to have swaged a portion of the inner cannula as taught by Akerfeldt in the method of Mittermeier as modified by Tretinyak in order to form the frustoconical interior surface that extends radially inward.

22. Tretinyak teaches the limitations of claims 18 and 19 as noted above and Mittermeier discloses the limitations of claim 20 as noted above.

23. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) as modified by Tretinyak (US 4,403,617), as applied to claims 17-20 above, and further in view of Jamshidi (US 5,807,275). Mittermeier as modified by Tretinyak does not expressly disclose a plurality of tongues and complementary grooves. Jamshidi teaches a tongue and groove connection having a plurality of grooves (40) extending radially into a cannula handle and a plurality of tongues (42) extending radially from a cap for engaging the grooves upon rotation of the cap relative to the handle. The tongue and groove configuration of Jamshidi provides a stop to ensure alignment and proper connection of the handles (column 4, lines 58-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the tongue and groove connection of Mittermeier as modified by Tretinyak to include a plurality of tongues and a plurality of grooves as taught by Jamshidi in order to provide a stop to ensure alignment and proper connection of the handles.

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24. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mittermeier et al. (US 6,063,037) as modified by Tretinyak (US 4,403,617) and Jamshidi (US 5,807,275), as applied to claims 21-23 above, and further in view of Strasser et al. (US 4,838,282). Mittermeier as modified by Tretinyak and Jamshidi does not expressly disclose a luer connector on the tool handle for connection to a syringe. Strasser teaches connecting a syringe to a luer connector of a tool handle in a conventional manner for applying a vacuum to a cannula for drawing in and retaining a biopsy specimen within the cannula (column 8, lines 26-37). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to have modified the assembly of Mittermeier as modified by Tretinyak and Jamshidi to include a luer connection on the tool handle for connection to a syringe in order to apply a vacuum to draw a sample into the cannula and retain the sample therein.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stewart (US 3,175,554) discloses a split biopsy needle.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Apanius whose telephone number is (571) 272-5537. The examiner can normally be reached on Mon-Fri 8am-4:30pm.

27. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

28. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MA

A handwritten signature in black ink, appearing to read "M. H. [unclear]", is located in the lower right quadrant of the page.